UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF ILLINOIS

The University of Chicago Medical Center
d/b/a University of Chicago Hospitals & Clinics
5841 South Maryland Avenue
Chicago, IL 60637-1470

Plaintiff,

vs.

Michael O. Leavitt
Secretary of the United States
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Defendant.

Case No. _____

COMPLAINT

NOW COMES Plaintiff, The University of Chicago Medical Center, d/b/a University of Chicago Hospitals & Clinics, ("Provider" or "Plaintiff") by and through its undersigned counsel, and for its Complaint against Michael O. Leavitt, Secretary of the United States Department of Health and Human Services ("the Secretary" or "Defendant"), states as follows:

I. INTRODUCTION

1. Plaintiff is a not-for-profit hospital that participates in the Medicare program, and at all times pertinent to this Complaint, it operated approved medical training programs for physician interns, residents, and fellows (collectively "residents").

2. Plaintiff took an administrative appeal from its notice of program reimbursement, as issued and revised by National Government Services (previously known as AdminaStar

Federal), Plaintiff's Medicare fiscal intermediary (the "Intermediary"), for the fiscal year ending June 30, 1996 ("FY 1996"). The appeal was based upon the Intermediary's improper exclusion of 50.86 full-time equivalent ("FTE") residents from the calculation of Plaintiff's Medicare reimbursement for indirect medical education ("IME"). Based upon an on-the-record hearing and other submissions by the Plaintiff and the Intermediary, the Provider Reimbursement Review Board ("PRRB") unanimously ruled that the Intermediary's exclusion of research training time from the Plaintiff's IME FTE count for reimbursement purposes was improper. The Secretary, by his delegate, the Administrator of the Centers for Medicare and Medicaid Services ("CMS"), notified the Plaintiff by letter dated October 11, 2007 that it had reversed the PRRB's decision.

3. This is a civil action brought to obtain judicial review of a final adverse agency decision regarding Medicare reimbursement rendered by the Secretary. The Plaintiff is seeking reversal of the Secretary's decision. The Secretary's decision violates the Medicare statute and regulations in effect during FY 1996, the Secretary's decision is arbitrary, capricious, an abuse of discretion, and otherwise contrary to law, and the Secretary's 2001 regulation excluding research from the IME FTE count contravenes the plain language of the Medicare statute.

II. JURISDICTION AND VENUE

4. This action arises under Title XVIII of the Social Security Act, 42 U.S.C. § 1395 et seq. (the "Act"), which establishes the Medicare program, and the Administrative Procedure Act, 5 U.S.C. § 551 et seq. (the "APA").

5. This Court has jurisdiction under 42 U.S.C. § 1395oo(f), 28 U.S.C. § 1331, 28 U.S.C. § 2201, and 28 U.S.C. § 1361.

6. Venue in this Court is proper under 42 U.S.C. § 1395oo(f)(1).

III. PARTIES

7. Plaintiff is a not-for-profit, acute care teaching hospital that is assigned Medicare Provider Number 14-0088. It operates graduate medical education programs for residents in various specialty and sub-specialty areas. These programs have been approved by the Accreditation Council for Graduate Medical Education ("ACGME") or otherwise qualify as approved medical residency programs eligible for Medicare reimbursement.

8. Defendant is the Secretary of the Department of Health and Human Services ("DHHS") and is the federal officer responsible for the administration of the Medicare Program pursuant to the Social Security Act. Defendant has delegated administration of the Medicare Program to CMS.

IV. THE MEDICARE PROGRAM AND APPEALS PROCESS

9. The Medicare program was established in 1965 by Title XVIII of the Social Security Act (the "Act"). As originally enacted, Medicare was a public health insurance program that furnished health benefits to participating individuals once they reached the age of 65. Over the years, it has been expanded to provide health benefits to qualifying disabled persons and to individuals suffering from end-stage renal disease.

10. Under the Act, an eligible Medicare beneficiary is entitled to have payment made by Medicare on his or her behalf for, inter alia, inpatient and outpatient hospital services provided by a hospital participating in the Medicare program as a provider of health care services.

11. The Secretary has delegated much of the responsibility for administering the Medicare program to CMS, formerly known as the Health Care Financing Administration (hereinafter collectively referred to as "CMS"), which is a component of DHHS. The Secretary,

through CMS, has contracted with fiscal intermediaries, which are typically private insurance companies, to perform many of his audit and payment functions under Medicare.

12. At the close of a fiscal year, a provider of services must submit to its intermediary a "cost report" showing both the costs incurred by it during the fiscal year and the appropriate share of these costs to be apportioned to Medicare. 42 C.F.R. § 413.24(f). The intermediary is required to analyze and audit the cost report and inform the provider of a final determination of the amount of Medicare reimbursement through a notice of program reimbursement ("NPR"). 42 C.F.R. § 405.1803.

13. A hospital may appeal the intermediary's determination of Medicare reimbursement to the PRRB pursuant to 42 U.S.C. § 1395oo(a) and 42 C.F.R. § 405.1835. The PRRB has jurisdiction over appeals from intermediary determinations if a hospital is dissatisfied with the intermediary's final determination, the amount in controversy is over $10,000, and the hospital requests a hearing within 180 days of the intermediary's determination. 42 U.S.C. § 1395oo(a). The PRRB decision may then be reviewed by the Administrator of CMS, who may reverse, affirm, or modify the decision. 42 U.S.C. § 1395oo(f). A hospital has the right to obtain judicial review of any final decision of the PRRB, or any reversal, affirmance, or modification of the PRRB's decision by the Secretary, by a civil action commenced within 60 days of the date on which notice of any final decision by the Board or Secretary is received. Id.

V. MEDICARE REIMBURSEMENT FOR IME

14. This case involves a controversy surrounding Medicare reimbursement for IME. The Medicare IME payment is determined through the cost reporting process outlined above. The process results in additional payments to teaching hospitals to compensate for the higher costs of training medical residents.

15. From the inception of the Medicare program until 1983, Medicare reimbursed hospitals for the costs of resident services on a "reasonable cost" basis. 42 U.S.C. § 1395f(b)(1), 42 C.F.R. § 405.421 (1983). Applicable cost reimbursement principles recognized that the training furnished to residents enhances the quality of care at a hospital. Thus, Medicare reasonable cost reimbursement rules have always defined the allowable costs of approved medical education programs to include resident stipends, the compensation paid by hospitals to teaching physicians, and other indirect overhead costs associated with these programs. See generally 42 C.F.R. § 405.421(g) (1983).

16. In 1983, Congress enacted the prospective payment system ("PPS") for inpatient hospital services. Under this system, the inpatient operating costs of hospitals and other health care providers are reimbursed based on prospectively-determined national and regional rates for each patient discharge, rather than on the reasonable operating costs for providing the services. Payments are made to hospitals via lump-sum amounts assigned to specific diagnosis-related groups ("DRGs"), determined by a patient's diagnosis at the time of discharge. See Social Security Amendments of 1983, Pub. L. No. 98-21, § 601(e); 42 U.S.C. § 1395ww(d). DRG payments are set to approximate the average cost of caring for a patient with a particular diagnosis in a well-run hospital. Thus, a hospital caring for a Medicare patient who falls into a given DRG receives a standard reimbursement amount for that patient (subject to certain geographic and other adjustments), regardless of the actual costs of caring for that patient. See 42 U.S.C. § 1395ww(d); 42 C.F.R. Part 412.

17. In accordance with the Medicare program's consistent recognition of the importance of medical education and its reimbursement for costs associated with such activities, Congress specifically addressed the need for the PPS to account for the costs associated with

medical education by providing for compensation to hospitals in the form of both "direct" and "indirect" payments. H.R. Rep. No. 98-25, 140-41 (1983); S. Rep. No. 98-23, 52-53 (1983). The direct graduate medical education payment ("DGME") is designed, as its name implies, to account for the direct costs associated with residency programs, such as salaries and fringe benefits for residents, while the IME payment is designed to compensate hospitals for the overall increased operating costs associated with operating a teaching hospital. 42 U.S.C. §§ 1395ww(h), 1395ww(d)(5)(B).

18. In creating the IME adjustment, Congress considered several factors that contribute to increased overhead costs at teaching hospitals, e.g., increased demands placed upon staff participating in the education process, the increased number of tests and procedures performed by residents as they learn their medical specialties, and the fact that teaching hospitals may attract sicker patients and provide more specialized services, among other factors. H.R. Rep. No. 98-25, 140-41 (1983); see also S. Rep. No. 98-23, 52-53 (1983).

19. The IME adjustment was thus created to act as a proxy measure for the level of teaching intensity at a hospital, calculated as a ratio of interns and residents to patient beds. 42 U.S.C. § 1395ww(d)(5)(B). The statute sets forth the IME calculation as follows:

$$[\{1+(R/B)\}^{n-1}] \times C = \text{"IME Adjustment Factor"}$$

Where: R = Number of Interns and Residents Assigned to the Hospital

B = Hospital's Beds

n = .405 (Measurement Factor for Teaching Activity)

C = Statutory Adjustment Factor.

Id. The resulting "IME adjustment factor" is then multiplied by the hospital's DRG payments for the cost reporting year to arrive at the IME reimbursement amount. Id.

VI. THE IME FTE COUNT

20. This case centers on the proper method for determining the variable "R," the number of interns and residents assigned to the hospital. In 1996, the relevant time period for purposes of this dispute, the regulations adopted by the Secretary required that, to be included in the IME FTE count, a resident must be in an approved teaching program and:

> be assigned to one of the following areas:
> (A) The portion of the hospital subject to the prospective payment system.
> (B) The outpatient department of the hospital.

42 C.F.R. § 412.105(g)(1)(ii) (1995).

21. In 1997, Congress further expanded the IME statute to include time spent by residents in a non-hospital setting, e.g., a physician's office, but only if the hospital incurs all or substantially all of the costs for the training program in that setting. 42 U.S.C. § 1395ww(d)(5)(B)(iv). In addition, to be counted at a non-hospital setting, Congress specifically required that the residents be engaged in patient care activities. Id.

22. In 2001, without any statutory change by Congress, the Secretary amended the Medicare regulation governing the IME payment. 42 C.F.R. § 412.105(f)(1)(iii)(B) (2001); 66 Fed. Reg. 39,828, 39,933-34 (Aug. 1, 2001). For the first time, the revised regulation restricted the resident count used to calculate a hospital's IME payment by excluding all time spent by residents in research not involving the care of a *particular* patient. 42 C.F.R. § 412.105(f)(1)(iii)(B) (2001). The Secretary's amendment imposed this patient care requirement for all residents, regardless where they were assigned, even though Congress had only imposed a direct patient care requirement on the subset of residents assigned to non-hospital settings. In amending the regulation to include a direct patient care requirement, the Secretary claimed to "reiterate our longstanding policy regarding time that residents spend in research and . . . to incorporate this policy in the IME regulations." 66 Fed. Reg. 22,646, 22,699 (May 4, 2001).

VII. FACTS SPECIFIC TO THIS CASE

23. The Provider is a teaching hospital that operates approved graduate medical education programs for residents and participates in the federal Medicare program administered by the Secretary.

24. The residents at issue in this Complaint were all enrolled in residency training programs that qualify as "approved medical residency training programs" for purposes of the IME payment regulations. The majority of these residency programs are approved by the ACGME, an organization recognized by CMS as an acceptable authority for determining whether a graduate medical education program is "approved." Other programs operated by the Provider qualify as Medicare "approved medical residency programs" because the training may count toward certification in a specialty or subspecialty. Among the standards for approval set by ACGME and the certification bodies is the requirement that residents participate in scholarly activities in addition to their clinical responsibilities. Accordingly, residents at the Provider participate in scholarly activities, such as medical research, in order to obtain their specialty or subspecialty certifications.

25. As a general matter, residents rotate through a number of training areas in connection with their chosen specialties. Nearly all residents are required to participate in a research rotation, during which the residents engage in research activities in furtherance of their specialty certifications. Residents remain assigned to the hospital during their research rotations.

26. For purposes of claiming Medicare reimbursement for FY 1996, the Provider included the time spent by residents in the hospital complex engaged in research and other scholarly activities when determining its resident FTE count for purposes of the IME calculation.

27. The Intermediary conducted an audit and subsequently adjusted the Provider's FY 1996 IME payment to reflect its exclusion from the IME calculation of time spent by residents

engaged in the portions of their approved residency programs involving research and other scholarly activities. This exclusion resulted in a loss of 50.86 FTE medical residents for FY 1996.

28. The Intermediary justified its exclusion of the residents' research time by asserting that, in order to include such time, the Provider was obligated to show that the residents' research involved direct patient care.

29. Although the regulatory patient care requirement for counting research time did not become effective until October 1, 2001, the Intermediary claimed that the new 2001 patient care requirement was but a clarification of longstanding policy, and that it was simply applying the existing policy when it issued its NPR excluding resident research time from the Plaintiff's FY 1996 IME payment. Such a policy was not, however, reflected in the extensive rules governing Medicare IME payment or in guidance materials issued by the Secretary at the time.

30. Upon receiving its NPR, the Provider timely filed notice of appeal with the PRRB, appealing the Intermediary's disallowance of resident time spent in research and other scholarly activities, along with other issues that are no longer in dispute.

31. On August 8, 2007, based upon an on-the-record hearing, the PRRB unanimously ruled that the Intermediary's exclusion of research time from the Provider's IME FTE count was improper. Citing its ruling in a prior decision, the PRRB reaffirmed that the Medicare regulation in effect during the cost reporting period at issue did not exclude research time from the IME FTE resident count, nor did it require resident time to be related to patient care. Furthermore, the PRRB found that the 2001 amendment to the IME regulation excluding non-patient care research time represented a change in policy that could not be applied retroactively to FY 1996. The PRRB also noted that it was undisputed that the residents at issue were enrolled in an approved

medical residency program and worked in either the inpatient PPS or outpatient areas of the Provider's facility.

32. By letter dated October 11, 2007, the CMS Administrator notified the Provider that it was reversing the PRRB's decision. The CMS Administrator's decision claimed that the Medicare program had a "longstanding policy" of excluding time spent by residents involved exclusively in research from the IME FTE count. In addition, contrary to the PRRB's factual finding and a stipulation of the parties, the CMS Administrator questioned whether the Provider had demonstrated that the FTE residents at issue were assigned to the areas of the Provider subject to inpatient PPS or the outpatient department.

33. This suit was timely filed within 60 days of the Provider's receipt of the Administrator's decision.

COUNT I
VIOLATION OF THE MEDICARE STATUTE

34. Plaintiff realleges and incorporates by reference paragraphs 1-33 as if fully set forth below.

35. Plaintiff asserts that the Administrator's decision is in error and that it has wrongfully denied the Plaintiff reimbursement to which it is entitled. The Secretary's construction of 42 U.S.C. § 1395ww(d)(5)(B) (describing the IME payment adjustment) is unlawful as applied to the Provider's cost report for FY 1996 because it contravenes the statute's plain meaning, its legislative history, and the regulations that were applicable at the time.

36. The statute in effect currently and during the Provider's FY 1996 cost reporting period requires the Secretary to "provide for an additional payment amount for ... hospitals [subject to the prospective payment system] with indirect costs of medical education. . . ." 42 U.S.C. § 1395ww(d)(5)(B). The law unambiguously requires the Secretary to take into account

all of the "indirect costs of medical education" when calculating the IME adjustment. The statute says nothing about the subset of medical education that constitutes direct patient care. Rather than imposing a direct patient care requirement, the statute provides hospitals with an increased payment for medical education regardless of whether that education involves patient care, research, or other activities related to medical education.

37. In 1997, Congress amended the Medicare statute to permit time spent in non-provider settings to be included in the IME FTE count, so long as these residents were engaged in direct patient care. Congress's specific mention of a patient care requirement only with respect to residents working outside the hospital setting plainly demonstrates that the requirement does not apply to residents working in the hospital.

38. The regulation in effect during FY 1996 unambiguously allows the Provider to include research time in its IME FTE count. During FY 1996, the regulation that governed the count of IME FTEs contained only two requirements: that the resident be "enrolled in an approved teaching program," and that the resident be assigned either to the "portion of the hospital subject to the prospective payment system" or to an "outpatient department of the hospital." 42 C.F.R. § 412.105(g). Accordingly, the plain language of the 1996 IME regulation permits the Provider to include research time as part of an approved residency program in its IME FTE count.

39. CMS asserted that its 2001 amendment to the IME regulation, inserting a direct patient care requirement for time spent in research, reiterated a "longstanding policy regarding time that residents spend in research and . . . [was done] to incorporate this policy in the IME regulations." 66 Fed. Reg. 22,646, 22,699 (May 4, 2001). CMS, in fact, had no such long-standing policy. Guidance provided by CMS officials, CMS manuals, and CMS Federal Register

notices do not support the existence of any policy that resident time spent in research activities should be included in the IME payment calculation, only if it involves direct patient care.

40. The Secretary's position is unlawful. The Intermediary wrongfully excluded research time from the IME FTE count for the Provider's cost report for FY 1996.

41. The Medicare statute requires the Secretary, CMS, and the Intermediary to include research time in the IME FTE count, and the Intermediary's exclusion of research time from the IME FTE count is a direct violation of the Medicare statute.

COUNT II
ARBITRARY AND CAPRICIOUS AGENCY ACTION

42. Plaintiff realleges and incorporates by reference paragraphs 1-41 as if fully set forth below.

43. The Intermediary's exclusion of research time from the IME FTE count, and CMS's and the Secretary's policy in support of that exclusion, is inconsistent with the statute and regulation that were in effect during the Plaintiff's FY 1996, is inconsistent with the Secretary's own interpretation of Medicare regulations during the time period in question, and is arbitrary, capricious, an abuse of discretion, and otherwise contrary to law, in contravention of the Administrative Procedure Act, 5 U.S.C. § 706.

COUNT III
UNLAWFUL RETROACTIVE RULEMAKING

44. Plaintiff realleges and incorporates by reference paragraphs 1-41 as if fully set forth below.

45. The 2001 IME regulation containing the research exclusion is a new, substantive rule which was only effective on October 1, 2001, after it was promulgated pursuant to notice and comment rulemaking. The Secretary may not punish the Provider for violating previously

unpublished rules. 5 U.S.C. § 552(a)(1). CMS may not apply its 2001 regulation retroactively because in 2001 Congress had not expressly authorized CMS to enact retroactive rules. The Secretary's attempt to apply the 2001 amendment to the Provider for activities that occurred prior to the regulation's effective date constitutes retroactive rulemaking in violation of the APA, 5 U.S.C. §§ 551 et seq.

COUNT IV
VIOLATION OF APA RULEMAKING PROCEDURES

46. Plaintiff realleges and incorporates by reference paragraphs 1-41 as if fully set forth below.

47. By imposing a direct patient care requirement for resident time spent in research during FY 1996, the Secretary impermissibly changed the substantive requirements of the IME regulation, in violation of the notice and comment rulemaking procedures of the APA, 5 U.S.C. § 553.

COUNT V
THE SECRETARY'S DECISION IS UNSUPPORTED BY SUBSTANTIAL EVIDENCE

48. Plaintiff realleges and incorporates by reference paragraphs 1-41 as if fully set forth below.

49. In reversing the PRRB's decision, the CMS Administrator ignored evidence in the administrative record regarding the assignment of the residents to areas of the hospital subject to the prospective payment system or to outpatient departments. The Administrator's decision to reverse the PRRB's findings is, therefore, "unsupported by substantial evidence," and must be set aside pursuant to 5 U.S.C. § 706(2).

COUNT VI
THE SECRETARY'S REGULATION IS UNLAWFUL AND INVALID

50. Plaintiff realleges and incorporates by reference paragraphs 1-41 as if fully set forth below.

51. The Secretary's current regulation at 42 C.F.R. § 412.105(f)(1)(iii)(B)–(C) is arbitrary, capricious, an abuse of discretion, and contrary to statutory law, and is therefore invalid, insofar as that regulation prohibits inclusion of research time in the IME FTE count when calculating IME reimbursement.

RELIEF REQUESTED

WHEREFORE, Plaintiff respectfully requests relief as follows:

1. A declaration by the Court that the Administrator's action reversing the decision of the PRRB is legally invalid and should be set aside as arbitrary, capricious, an abuse of discretion, not in accordance with the law, and unsupported by substantial evidence in the record.

2. A declaration by the Court that the Intermediary's and the Secretary's exclusion of research time from Plaintiff's IME FTE count is arbitrary, capricious, unreasonable, unlawful, and invalid.

3. A declaration by the Court that Secretary's current regulation at 42 C.F.R. § 412.105(f)(1)(iii)(B)–(C) is arbitrary, capricious, an abuse of discretion, and contrary to statutory law, and is therefore invalid, insofar as that regulation prohibits inclusion of research time in the IME FTE count when calculating IME reimbursement.

4. An order from this Court requiring the Secretary to add 50.86 FTEs to the Plaintiff's IME FTE count for FY 1996 and to recalculate, within ninety days, Plaintiff's IME reimbursement accordingly.

5. An order from this Court requiring the Secretary to pay Plaintiff interest on the payments resulting from the Court's order, pursuant to 42 U.S.C. § 1395oo(f)(2).

6. An order from this Court awarding Plaintiff the costs and fees incurred in this litigation and granting such other relief in law and/or equity as this Court may deem just and proper.

Respectfully submitted,

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